Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt

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ISNAR Country Report 62

Agricultural Genetic Engineering Research Institute

International Service for National Agricultural Research

AGERI

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ACRONYMS

ABSP	Agricultural Biotechnology Support Project (MSU)
AGERI	Agricultural Genetic Engineering Research Institute
ARC	Agricultural Research Center
BSO	biological safety officer
Bt	*Bacillus thuringiensis*
CAS	Central Administration for Seeds
CASC	Central Administration for Seed Testing and Certification
CASP	Central Administration for Seed Production
CIP	Centro Internacional de la Papa — International Potato Center
GATT	General Agreement on Tariffs and Trade
GMO	genetically modified organism
IBC	Institutional Biosafety Committee
IBS	ISNAR's Biotechnology Service
ISNAR	International Service for National Agricultural Research
MALR	Ministry of Agriculture and Land Reclamation
MSU	Michigan State University (USA)
NBC	National Biosafety Committee
PTM	potato tuber moth
SPS agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
SRC	Seed Registration Committee
TRIPs	Trade Related Aspects of Intellectual Property Rights agreement
UNEP	United Nations Environment Programme
UPOV	Union pour la Protection des Obtentions Végétales — International Union for the Protection of New Varieties of Plants
VCU	Value of Cultivation and Use
Virginia Tech	Virginia Polytechnic Institute and State University (USA)
WTO	World Trade Organization
ZYMV	zucchini yellow mosaic virus

EXECUTIVE SUMMARY

During the past decade, national biosafety systems have gained importance as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. This Country Report presents an analysis of the present status of the biosafety system in Egypt and its impact on the commercialization of genetically modified organisms (GMOs). The specific objectives of the report are:

1. to assess the efficacy of biosafety policies and procedures associated with the introduction of biotechnology products in Egypt;
2. to develop recommendations for enhancing the operation of Egypt's biosafety system and minimizing potential constraints to technology transfer;
3. to identify areas where ISNAR and other international providers can provide further assistance.

The report includes a description of the organization and operation of Egypt's biosafety system, and discusses the larger context for GMO commercialization. Recommendations emerging from this study include (1) specific suggestions for revising Egypt's biosafety guidelines, (2) ideas for improving the functioning of national and institutional biosafety committees, (3) recommendations for strengthening biosafety review and decision making, and (4) developing means of actively disseminating information to the wider biotechnology community and the public.

Findings and recommendations in the report may serve as the basis for discussions to strengthen and adapt the biosafety system to the changing context for biotechnology products in Egypt.

Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt

I. INTRODUCTION TO THE STUDY

Techniques of modern biotechnology are viewed by many agricultural scientists as a new and promising tool for crop improvement and novel uses of plants, animals, and microorganisms. Concerns about the safety of GMOs to human health and the environment, however, moderate the rate of GMO product development and deployment. National biosafety systems are intended to serve as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. However, establishing a system for biosafety review has many facets and associated challenges, and, apart from defining national guidelines, will require investments in people responsible for implementing and managing the system.

ISNAR's Biotechnology Service (IBS) and Virginia Polytechnic Institute and State University (Virginia Tech) set up a collaborative research project to (1) assess the impact of genetically engineered crops being commercially released in partner countries and (2) review biosafety policies and procedures associated with the introduction in order to assess the efficacy of their biosafety systems. The governments of the Netherlands, Switzerland, and the UK provide financial support for the project.

The joint project will lead to a set of recommendations addressing identified gaps in the technical, human, and information resources needed to strengthen biosafety capacity. It was decided to conduct two country case studies to review biosafety policies and procedures, the first of which would be Egypt. Egypt was selected as a partner country in the study based on its experience as a developing country in designing and implementing a national biosafety system as early as 1993, and in reviewing applications for contained and commercial release of genetically modified crops.

This report provides a review of the present status of the biosafety system in Egypt and its applicability to the commercialization of GMOs. The specific objectives of the report are:

1. to assess the efficacy of biosafety policies and procedures associated with the introduction of biotechnology products in Egypt;
2. to develop recommendations for enhancing the operation of Egypt's biosafety system and minimizing potential constraints to technology transfer;
3. to identify areas where ISNAR and other international providers can provide further assistance.

The study focused on the human and mechanistic aspects of the Egyptian biosafety system. Major points of interest were: (1) the organization, membership, and operations of the National Biosafety Committee (NBC), (2) the nature and availability of information on biosafety procedures and requirements, (3) the path of regulatory review and approval leading to commercial release, (4) the extent of public involvement in biosafety matters, and (5) the personal experiences of applicants and reviewers in dealing with the biosafety system. Findings and recommendations in the report may serve as the basis for discussions to strengthen and adapt the biosafety system to the changing context for biotechnology products

in Egypt. They may also serve to advance efforts in the areas of public acceptance, technology transfer and regulatory harmonization.

Rationale

Unlike "conventional" new products, products of agricultural biotechnology use novel gene combinations to confer altered and often unique phenotypes. Questions and uncertainty about their potential to harm the environment or human health have raised caution flags in the rapid development and deployment of the technology and its products. Accordingly, national biosafety systems have been established in more than 50 countries to evaluate proposed uses of GMOs and their products. Guidelines have been written[1], a review process has been instituted, and people have been trained to make informed decisions about small and large-scale releases. Biosafety systems thus act as gatekeepers to the use of biotechnology.

In the early years of operation, procedures for each step of biosafety review and approval are established as and when needed, until the system becomes fully implemented. Particularly during this initial period, the strengths, weaknesses, bottlenecks, gaps, complexities, and virtues of the system become evident. Certain aspects of the system may unnecessarily impede the process or undermine the scientific basis of product review, hindering responsible and efficient decision making. Additionally, the continuous accumulation of new information helps support and strengthen risk assessment and risk management practices. Periodic examination of the system and the elements within it provides an opportunity to develop recommendations for improving the efficacy of the biosafety system.

Egypt is among the developing countries most advanced in the adoption and use of agricultural biotechnology. The Agricultural Genetic Engineering Research Institute (AGERI), established in 1990, is a center for state-of-the-art research conducted by a staff of more than 20 PhD scientists and about 60 MSc- and BSc-level researchers. More than 40% of the staff with advanced degrees are faculty or advanced students at other Agricultural Research Center (ARC) institutes and universities with agricultural biotechnology research programs. They work at AGERI on a temporary basis (Chemonics 1998).

Research activities at AGERI focus on developing pest-resistant and stress-tolerant varieties of crops such as tomato, maize, Faba bean, cotton, and potato. The bulk of research is directed towards developing GMOs tailored for local conditions and consumer preferences. In addition, multinational companies have been seeking permission to import their GMO crops for testing in Egypt since 1995. Several genetically modified crop varieties now have undergone multiple rounds of field trials and are being considered for commercialization. As these first GMOs move through the biosafety system towards commercial release, insight is gained as to how the system is operating. They may reveal unrecognized and unintended impediments to their biosafety evaluation and, ultimately, their commercial release.

Framework for the study

The review of biosafety policy and procedures in this study is structured around the four elements of national biosafety systems as described by Traynor (1999). These are: (1) written

[1] National biosafety guidelines are available on the Internet by the Biosafety Information and Advisory Service (BINAS), a service of the United Nations Industrial Development Organization (http://binas.unido.org/binas).

guidelines or regulations for use and release of GMOs, (2) the people who propose releases or conduct biosafety reviews, (3) the risk assessment/risk management review process, and (4) mechanisms for feedback to improve the system through experience. This view of biosafety systems is presented in more detail in Section III below.

Primary sources of information for the study were personal interviews and a review of documents pertaining to biosafety. IBS and Virginia Tech developed a set of questions (Annex 1), which served as a starting point for interviews with two groups of people: (1) members of the National and Institutional Biosafety Committees who serve as reviewers and decision makers, and (2) applicants from public research institutes and private companies who are the "customers" of the biosafety system in their pursuit of commercial release. The wide-ranging interviews sought to elicit individual perceptions of, and experiences with the Egyptian biosafety system. A list of those interviewed is included in Annex 2.

Biosafety reviewers were asked about their awareness of environmental risk issues, training in risk assessment and risk management, the review process, the basis for specific decisions, institutional support, sense of farmers' attitudes and public opinion about GMOs, and mechanisms for providing information to farmers and the general public. Applicants were asked about their level of awareness of biosafety issues and operations of the biosafety system, knowledge of sources of information and application forms, status of GMO importation, testing, and commercialization, experiences in securing approvals, and understanding of farmer and public opinion. All interviewees were asked for suggestions on ways to improve any part of the system to make it more efficient and effective.

The documents reviewed include the following:

- Biosafety Regulations and Guidelines-Egypt (1994)
- Chart of Permits Issued by the NBC-Egypt from 1995-1999
- NBC Membership List (1999)
- Permit Application Forms
- Protocol for Permit, Register and Release of Genetically Modified Plants in Egypt (1999)
- Minutes of NBC Meetings (translated)
- Survey of Extent and Impact of Releasing LMOs and Its Commercial Products (1999)
- Policy and Procedures for Release of Crop Varieties (1998)

English translations of application and decision documents were not available; however, details of their contents were discussed during interviews.

The report based on the interviews and document review is organized into six sections plus references and appendices. Section I describes the research project and methodology used for the study. Section II first presents a model biosafety system, as applied in the joint project between IBS and Virginia Tech, and a detailed view of the Egyptian system. The broader context for biotechnology in Egypt is presented in Section III. Included are the framework of policies and laws for the development and use of agricultural biotechnology products, trade considerations, and the status of public debate regarding biotechnology. The resultant paths of testing and regulatory review taken by three genetically engineered crops nearing commercialization are given in Section IV. Findings of the study are presented in Section V, with corresponding recommendations given in Section VI.

II. ANALYSIS OF BIOSAFETY SYSTEMS

Four common elements

In developed and developing countries alike, decisions as to the appropriate release of GMOs are made in accordance with written guidelines, as interpreted by committees, which conduct biosafety reviews based on a growing body of scientific information and experience. The guidelines, people, review process, and mechanisms for feedback are the four common elements that comprise the framework of a national biosafety system[2]. The four elements are discussed in general below, followed by reference to the situation in Egypt.

Guidelines

Documents implementing biosafety policy may be in the form of new regulations, adaptation of existing regulations, or non-legislative guidelines issued, for example by Ministerial Decree. Such documents typically authorize the formation of national and institutional Biosafety Review Committees, specify their respective duties and membership, and describe application and review procedures for environmental releases of GMOs.

In setting forth policies and procedures for biosafety oversight, the guidelines should clearly articulate what is subject to biosafety review and what is not. Do they apply to products of all modern biotechnologies or only to rDNA research? Are laboratory and greenhouse experiments included, or only releases into the environment? Do they apply to recombinant vaccines and pharmaceuticals or non-agricultural applications such as industrial fermentation technologies? Are there provisions for commercializing products? How will food safety be evaluated? Which ministries are to be involved?

As a further consideration there may be existing guidelines for laboratory research with hazardous chemicals, radioisotopes, pathogenic organisms, and other situations that pose biosafety issues. Thought should be given as to whether or not biosafety with respect to biotechnology should stand alone or be integrated with these other areas.

People

Applicants seeking to conduct field tests of GMOs and members of review committees who must make a decision to approve a proposed release should be equal partners in ensuring the safe use of biotechnology products. Both need to be familiar with the environmental risk/benefit issues associated with biotechnology products and have a working knowledge of the biosafety review process. The quality of the review they conduct and the decisions they make is a direct outgrowth of their training and experience. Thus the challenge is to build a core of knowledgeable people who understand the issues and their potential consequences, and who can systematically evaluate the risks and benefits of a proposed GMO release.

The Review Process

Biosafety review is a systematic evaluation of the GMO, the site where it will be released, and the conditions under which the release will be conducted. If a potential risk is identified, appropriate management procedures are built into the release plan to reduce the risk to an acceptable level. Although the emphasis of most biosafety reviews is on potential risk,

[2] For a more detailed discussion of the four elements involved, see Traynor (1999).

applicants and reviewers need also to consider the potential benefits of a test that may lead to eventual use of the GMO, and recognize that *not* proceeding may carry risks as well.

Not surprisingly, there are ongoing discussions over what constitutes a risk, what is the limit for an acceptable risk, and what consequences are of concern. Risk identification and assessment is further challenged by the necessarily subjective interpretation of often inadequate scientific data and information. Currently, biosafety reviews focus on a limited number of environmental issues associated with the release of transgenic crops, i.e., weediness, gene flow, toxicity, and pest and pathogen effects. However, it is incumbent upon reviewers to recognize any unique aspects of a particular crop/gene/environment combination that may present other concerns.

Mechanisms for Feedback

Agricultural biotechnology remains a field in which risk/benefit assessments and risk management decisions are hampered by knowledge gaps and a lack of data. Thus it is critical that biosafety systems include mechanisms through which new information and accumulated experience can be incorporated. Technical information and scientific data gathered from previously approved releases can be used to support subsequent biosafety reviews. Field test information and assessments from other countries may be useful, so long as potentially significant differences in the environment, affected ecosystems, and agronomic practices are recognized.

Review committees may specify reporting and record keeping requirements as a condition of approval. This type of feedback allows institutional and national biosafety committees to gather information and identify emerging issues of local or regional importance. The relevance and usefulness of such feedback, however, will depend on the quality of data submitted. If, for example, monitoring to determine survival of a GMO or detect transgene flow via pollen movement is required, it should be conducted in order to provide scientifically valid data, rather than anecdotal reporting.

A periodic re-evaluation of guidelines and implementation procedures gives applicants, reviewers, administrators, regulators, and the public an opportunity to assess how well the system is working. Are applications reviewed on a timely basis? Is the burden of paperwork excessive or redundant? Can the review process be streamlined without compromising environmental responsibility? Are there new factors to consider, such as administrative reorganization or a change in the budget? Is the public satisfied that their health and safety concerns are being properly addressed?

To summarize, establishing and maintaining a functional, effective biosafety system presents challenges at every step. It requires adequate and dependable funding. It entails education and coordination across government ministries, universities, and research institutes, private-sector interests, individual scientists, and the public. Significant investments may be needed in training and human resource development, information and communications systems, facilities, and follow-up activities. The elements in a biosafety system are interrelated and interdependent. Therefore efforts to strengthen any one part will ultimately strengthen the entire system and the biosafety decisions coming from it.

Egypt's Biosafety System

Egypt's effort to address environmental responsibility for products of biotechnology was set in motion in 1992 by the terms of collaboration between AGERI and the Agricultural Biotechnology Support Project (ABSP). ABSP is a project at Michigan State University (USA) supported by the US Agency for International Development (USAID), which supports collaborative research and policy development in agricultural biotechnology in partner countries. From the outset, it was understood that transgenic products developed under the agreement would not be transferred and tested in Egypt unless there was an adequate mechanism for biosafety review.

During the period 1993–99, the ABSP-AGERI collaboration supported biosafety awareness and implementation with a series of internships, consultations and workshops. Around 10 AGERI scientists and managers have attended a biosafety internship program at Michigan State University. In 1993, one of them was assigned the full-time responsibility of drafting biosafety guidelines for laboratory, greenhouse, and field experiments with GMOs. To further biotechnology research at AGERI, the ABSP project supported construction of a biocontainment greenhouse facility completed in 1995.

Egypt's national biosafety system was formally instituted by the Ministry of Agriculture and Land Reclamation (MALR) in two decrees issued early 1995. Ministerial Decree No. 85 (January 25, 1995) establishes a National Biosafety Committee (NBC); Ministerial Decree No. 136 (February 7, 1995) adopted biosafety regulations and guidelines for Egypt.

The system involves several ministries, organizations, and/or government agencies involved with the importation, exportation, and local production of natural products. Within the Ministry of Agriculture and Land Reclamation, the Central Administration for Seed Testing and Certification (CASC) controls, tests, and registers new plant varieties. In the Ministry of Health, the Supreme Committee for Food Safety ensures the safety of food production and consumption and controls food import permitting. The National Organization for Drug Control and Research oversees pharmaceutical research and controls distribution. The Ministry of Trade and Supply controls the import and export of products. In the Ministry of Industry, the Egyptian Organization for Standardization and Quality Control sets the standards for food and industrial products whether imported or locally produced. In the Ministry of Environment, the Egyptian Environmental Affairs Agency ensures implementation of the Environment Protection Law in Egypt.

Developers of the biosafety system adopted an approach in which components were added only as they became necessary. For example, testing requirements for GMO seed certification were not clarified until the first applications for commercial release were submitted to the Seed Registration Committee. Similarly, no decisions on the labeling of GMO-based food products have been made, as those products are not yet being sold in supermarkets.

Guidelines

Biosafety regulations and guidelines were published in draft form in January 1994 (MARL 1994). Research materials from the ABSP-AGERI collaboration were nearing completion of greenhouse tests, providing impetus to move forward with developing biosafety policy and procedures for conducting GMO field tests. The guidelines were intended to describe the

modalities of use, handling, transfer, and testing of GMOs; they address laboratory practices, greenhouse containment, and small-scale field testing.

The guidelines describe the structure, composition, roles, and responsibilities of the NBC. NBC duties include formulating, implementing and updating biosafety guidelines; conducting risk assessments; issuing permits; coordinating with national and international organizations; providing training and technical advice; and, reporting to governmental authorities.

The guidelines call for establishment of an Institutional Biosafety Committee (IBC) at all institutions conducting recombinant DNA (r-DNA) research. The IBC is responsible for establishing a facility inspection program; assembling a set of appropriate institutional guidelines that comply with the NBC guidelines; assessing facilities, practices, and procedures; periodically reviewing r-DNA research being conducted in the institute; adopting emergency plans for accidental spills and personnel contamination; periodically reviewing containment measures; overseeing IPR matters as they apply to the institute; and reporting annually to the NBC.

People

Egypt's National Biosafety Committee is the official body responsible for ensuring that biotechnology products are used safely and facilitating access to modern biotechnology generated abroad. Members of the NBC are appointed by the Chair, HE Prof. Youssuf Waly, Deputy Prime Minister and Minister of Agriculture and Land Reclamation. Terms of service are open-ended, thus the committee now includes some members with five years experience.

The initial committee consisted of 10 members; subsequent appointments have expanded it to 30. Current members include: seven representatives of the Ministries of Agriculture, Health, Environment, Industry, and Commerce; a representative of the Egyptian Academy of Science and Technology; 12 members from academic institutions; an attorney; eight people from government research institutes; and a seeds expert. Based on area of expertise, members are appointed to one of three subcommittees specializing in agriculture (crops), environment (biopesticides, biofertilizers, agents for bioremediation), and health (pharmaceuticals, human and veterinary vaccines).

IBCs are to be composed of people with expertise in r-DNA technology, biological safety and physical containment, policies and applicable law, and a biological safety officer (BSO). The BSO reports to the IBC regarding follow-up on his duties, which include enforcing approved policies and regulations; ensuring that all facility standards are rigorously followed; ensuring safety of all facility work and prevention of the accidental escape of GMOs; maintaining data on all aspects of biosafety related to mandated crops; checking and advising on biosafety issues on a day-to-day basis; and monitoring worldwide biosafety requirements for r-DNA technology.

The Review Process

A standardized Permit Application form is used to request NBC approval of a proposed greenhouse study or field test (Annex 6). Upon submission of the application, all members of the appropriate subcommittee are given copies and one member is designated the Principal Investigator. The Principal Investigator, who may consult with other subcommittee members, is assigned to thoroughly review the application, visit the field test location, inspect the facilities, and submit a report to the NBC. The proposed release is then discussed at a meeting

of the full NBC, where a decision is made to issue or deny the requested permit. Where a Committee member is the applicant or had been involved in the research leading to the GMO to be considered, that member does not vote on the application.

Approval may stipulate certain conditions or practices during field tests that the NBC deems appropriate to the proposed release. For approved tests, the Principal Investigator advises institutional staff regarding standard and specific biosafety practices and techniques.

Between January 1996 and July 1999, 25 applications were reviewed by the NBC. Twelve of these were for open field tests, 11 for work in the biocontainment facility at AGERI, and another two were for both greenhouse and field testing. These applications involved seven products: potato, musk melon, tomato, squash, sugar cane, maize, and cucumber, and a recombinant veterinary vaccine. A complete list of permits issued to date is in Annex 5.

Procedures for field tests: Applications to field-test genetically modified plant material are submitted to the Chair of the NBC. Genetically modified material to be imported requires an import permit that must be obtained in advance from the Supreme Committee on Food Safety, Ministry of Health. Requests should be made a minimum of eight weeks prior to the proposed initiation of the importation or field test.

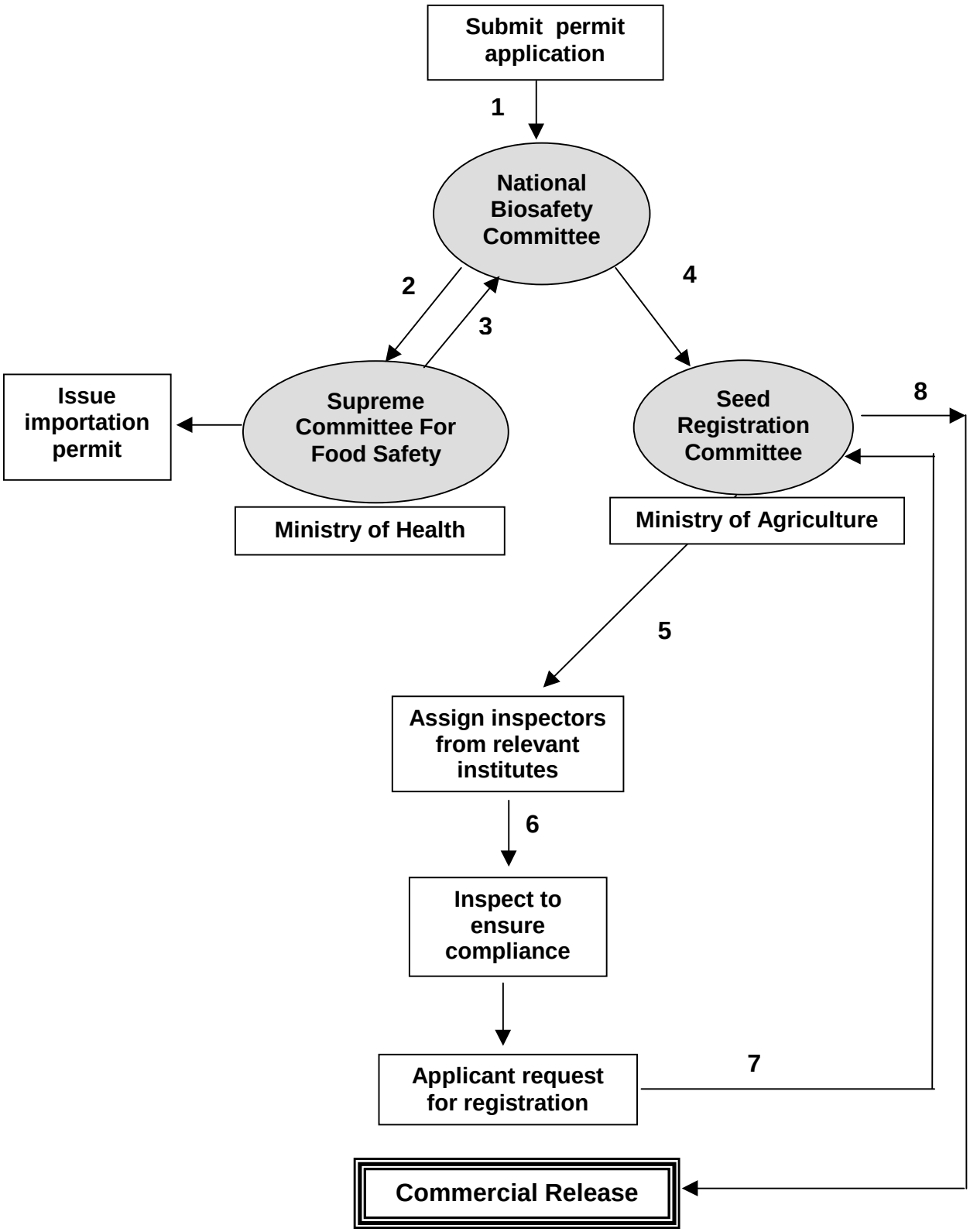
The NBC, serving as the lead agency, sends duplicate copies to secondary agencies for their assessment (i.e. Supreme Committee on Food Safety), as applicable. Reviews from the secondary agencies are returned to the lead agency, and a final assessment performed. From this a decision is made whether to authorize the field test. Any mitigation procedures required will be determined before authorization. Applicants are required to indicate which information the application is confidential, such as exact trial sites, plasmid maps, exact genetic change, or others to be specified. Other information may initially be designated confidential, however its confidentiality is subject to provisions in the Access to Information and Privacy Act.

Field-test permit applications must describe the plant species modified to exhibit a specific trait, to be tested at a specific location in a specific year. For instance:

- Canola (*B. napus*) lines, one modified to show tolerance to a specific herbicide resulting from the insertion of one specific gene, and another modified to show tolerance to certain insects by the insertion of the delta endotoxin gene from *Bacillus thuringiensis*, both of which will be tested in a small-scale field trial at one location in one year, are considered as two field tests. A separate assessment is made on each of the two different genetic constructs.
- Canola modified to be resistant to a specific herbicide as a result of one specific gene, to be tested for agronomic performance in small-scale field trials at six locations in the same year, will be considered as six field tests. The same modified canola to be tested at the same six sites over two growing seasons will constitute twelve field trials.

Procedures for commercial releases: Procedures for commercializing GMO crops were established in 1998 by Ministerial Decree No. 1648. The sequence of steps and interactions among government agencies are diagrammed in the flow chart on the following page (figure 1).

Figure 1. Steps for Commercial Release of Genetically Engineered Plants in Egypt



For varieties produced within Egypt, the process is as follows:

1. The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, and other relevant information. The applicant also provides data from food and feed safety studies and evidence supporting a determination of low or negligible environmental risk. Where applicable, the applicant provides documents indicating approval of similar GMOs for release in their country of origin.
2. The application form is submitted to the NBC, which, after examination and approval, forwards it to the Seed Registration Committee for their preliminary approval to proceed with standard field trials conducted at several locations. The SRC assigns a team of qualified inspectors drawn from relevant ARC units and/or private certified laboratories to supervise cultivation, ensure adherence to any biosafety requirements, confirm the new phenotype, and evaluate agronomic performance.
3. The NBC has the right to confirm the nature of the genetic modification by taking samples from the field for molecular analysis.
4. After successful completion of the field trials and submission of a report to the NBC, the NBC authorizes the applicant to submit an application to the Seed Registration Committee for final approval to commercially release the new variety. Pending this, three years or seasons of agronomic performance trials are conducted under the supervision of the SRC.

The process for securing commercial release approval for crops genetically engineered outside of Egypt has an added step. The applicant must first obtain a permit for importing the initial seed material from the Supreme Committee for Food Safety, Ministry of Health. The permit is then presented to the NBC and the Seed Registration Committee, after which the seed is imported into the country. From this point forward, the remaining steps in the approval process are exactly the same as for GMOs developed within Egypt.

Mechanisms for Feedback

Data from local and external field tests, findings reported in the scientific literature, reports from risk assessment studies, and proceedings from conferences and workshops are among the potential sources of feedback into the biosafety system. Currently, acquisition of this information is an individual activity on the part of some applicants and biosafety committee members.

In Egypt, approval by the NBC to conduct a field test does not require the applicant to submit a report at its conclusion. During seed registration trials, monitoring is carried out by an appointed team of inspectors. As the purpose of the trials is to evaluate variety performance, monitoring is conducted primarily to ensure compliance with biosafety requirements, not to collect biosafety data.

Most NBC members and scientists at AGERI and other ARC institutes have at least some form of Internet access. Whether or not people retrieve and use the available information, however, is a personal decision based on the individual’s ease of connection, amount of access time, familiarity in navigating the Internet, and degree of interest.

Worldwide field-test data are often regarded as particularly useful to biosafety practitioners. However, the purpose of most small-scale tests is to evaluate a GMO's phenotype under field conditions and check for significant changes in crop yield and quality. As such, it is rare for a field test to generate valid biosafety data unless it has been set up to include a risk assessment component. Nonetheless, accumulated positive experience from numerous field tests of the same or similar GMO, in Egypt or in other countries, tends to support decisions to approve a new application.

The peer-reviewed scientific literature is a primary source of current findings in risk assessment research, ecological studies, and food safety reports. Access to such publications depends largely on the individual's proximity to a library that maintains subscriptions to relevant journals.

A small number of NBC members have attended international meetings on biosafety and risk assessment research. Similarly, several AGERI and university scientists have been able to participate in conferences and get up-to-date information related to biosafety data. Financial support for participation is a chronic limiting factor. It is likely that more people would take part, and bring home the benefits, if given the opportunity.

III. CONTEXT FOR BIOSAFETY AND GMO COMMERCIALIZATION

Biosafety regulation of genetically modified plants should be viewed in the context of crop variety development, release and distribution in Egypt, which determines the feasibility of a new product entering commercial release. Elements of this wider context described in this section include Egypt's seed registration system, regulations regarding intellectual property, and the public debate and consequent consumer response to genetically modified food.

Introduction

Egypt, with an estimated population of 70 million in the year 2000, a limited area currently under cultivation (5% of total land area), and limited water resources providing less than 1000 cubic meters per person per year, is facing serious challenges in agricultural development (Madkour 1998). To meet the growing demand for food and fiber and to fulfill the goal of self-reliance, Egypt must:

- optimize consumption of water resources through use of drought and heat tolerant crop varieties;
- increase production of agricultural crops by increasing both yield per unit area and total land area under cultivation;
- protect the natural environment and minimize pollution;
- improve public health; and
- develop industrial fermentation sectors in pharmaceuticals, chemicals, enzymes, and other products.

In this respect, biotechnology's contributions to improved food production, health care, and environmental protection can play an important role in fostering economic and social progress in Egypt. This can be achieved, for example, through improved seeds with high productivity under conditions of drought, heat, and pest and disease pressure, new vaccines, novel food ingredients, and new techniques for the rapid detection and identification of pathogens and toxicants. Egyptian government leaders recognize the importance of

biotechnology as a tool for national and global development and have set excellence in biotechnology and genetic engineering as a national goal (Madkour 1998).

Egypt's Seed Registration System

The seed registration system plays a central role in the process leading to commercialization of agricultural GMOs. Seed registration in Egypt follows a well-established procedure controlled by several organizations under the umbrella of the Ministry of Agriculture and Land Reclamation (MALR). The Central Administration for Seeds (CAS), an under-secretariat of MALR, has overall authority for policy and procedures regarding registration and release of all seed in Egypt.

Once confined field tests have been conducted, applicants submit a package to the National Biosafety Committee to support a finding of low or negligible environmental risk. Upon review and approval, the application is forwarded to the Seed Registration Committee, which grants approval to begin three year (or three season) quality and performance evaluation, which is standard for all new varieties. Only upon successful completion of these trials will a conventional or GMO variety be approved for commercial sale. Thus seed registration is the final step in commercial release of genetically engineered crops.

The sections below describe the seed industry and its organization, then present the latest ministerial decrees relevant to the registration and release of plant varieties, both conventional and genetically modified.

Structure of the Seed Industry

In 1993, the Ministry of Agriculture initiated the implementation of a market economy policy for agriculture by issuing a decree reorganizing the seed sector. The Decree separated seed certification, quality control, marketing control, and law enforcement activities from seed production activities. This change continues to gives a strong push for complete privatization of the seed sector and improved performance in quality control and seed certification organizations, leading ultimately to improved seed quality. The following agencies play a key role in Egypt’s seed sector:

- The Agricultural Research Center (ARC): ARC has 17 research institutes and support organizations. It has the primary responsibility for crop improvement research, cultivar development and testing throughout the country. ARC supervises national field crop breeding programs for cereals, fiber materials, oils, legumes, fodder, and sugar. The majority of field crop varieties and, to a lesser extent, vegetable varieties have been developed by the ARC research institutes.
- The Central Administration for Seed Testing and Certification (CASC): CASC, established in 1995, is the agency responsible for seed quality control, seed legislation and policy enforcement. CASC reviews all relevant legislation, updates and prepares rules required to control all seed activities, and works to integrate and harmonize the seed legislative framework. CASC is the designated seed certification authority and performs lab and field testing for certified seed and lab testing for the uncertified seed.
- The Central Administration for Seed Production (CASP): CASP administers and advises ARC on requirements for foundation and registered classes of seeds and plants. The

agency supervises and contracts with seed growers to multiply seed. CASP is headquartered in Giza with offices in the governorates.

- Seed companies: There are 66 registered seed production companies specialized mainly in seed of hybrid maize, sorghum, sudangrass forages, sunflower, some vegetable seeds, and seeds of clover and alfalfa. In addition, 53 companies are registered for seed import and 148 for seed export.

Seed Industry Regulation

The Egyptian Seed Industry started in 1922 when a cottonseed production and distribution unit was established in the Ministry of Agriculture. Later, activities of this unit were expanded to include seed production of other crops. This unit was progressively upgraded until being designated an Under Secretariat of MALR in 1980.

The Ministry of Agriculture has statutory responsibility for the establishment, operation, and control of seed activities in Egypt according to Law No. 53 of 1966. Due to the seed industry's role as an important tool in raising agricultural productivity, MALR has taken the initiative to support and strengthen the seed industry infrastructure. The Ministry has started to liberalize this vital economic sector and to encourage private sector participation, especially in hybrid seed production. The investments which have been pumped into the seed industry over the last 15 years exceed 200 million Egyptian pounds (around US$ 600,000), which represents more than 100 times what had been spent during the previous 30 years.

Latest Ministerial Decrees for Registration and Release of Plant Varieties

During the period 1997–99, a number of Ministerial Decrees were issued to accommodate changes in the Ministry of Agriculture's role in plant breeders' rights and liberalization of the agricultural sector.

(1) Decree No. 242/1997, Ministry of Health: This decree prohibits importing any foodstuff produced through GMOs, unless its safety is confirmed. The act also necessitates that a certificate should accompany any imported seeds from the country of origin, confirming that these seeds were not produced from untested genetically modified (GM) plants. GM plants or seeds can be imported if previously approved for use in the country of origin and deemed safe.

(2) Decree No. 82/1998, Ministry of Agriculture: This decree establishes policy and provides guidance on procedures for the release of crop varieties developed by the ARC (Annex 3). It makes no distinction between varieties developed through conventional breeding and those derived by genetic engineering. Variety identification, or Distinctness, Uniformity and Stability (DUS) tests are conducted in one location during seed multiplication. Model descriptors issued by the International Union for the Protection of New Varieties of Plants (UPOV) are used for a comparative evaluation against standard varieties as defined by the relevant Crop Seed technical committee, which are grown in parallel with the new variety. Variety performance or Value of Cultivation and Use (VCU) tests examine the new variety's agricultural, industrial, and economic value as compared with other superior varieties in use. Such tests are conducted in more than one location to ensure that the variety tolerates a diversity of local environmental conditions. The candidate variety is recommended to be registered only when all required tests have been satisfactorily completed.

(3) Decree No. 1648/1998, Ministry of Agriculture: This decree confirms the authority and responsibility of CAS for releasing GM as well as conventional seeds. It describes procedures for obtaining a small-scale release permit for a new genetically engineered crop variety, registering it, and releasing it for commercial use. It outlines important steps to be followed by government or private sector applicants, as well as other local or foreign organizations seeking to commercialize their products. The decree specifies the roles and responsibilities of the NBC, the Seed Registration Committee, and the Committee for Food Safety. A draft paper outlining the protocol for commercial release of GMO crop varieties was developed by a panel of experts from MALR and the USAID. The final document was approved by deputy Prime Minister and Minister of Agriculture in July 1999 (Annex 4).

(4) Decree No. 702/1999, Ministry of Agriculture: This decree adds DNA fingerprinting to the required protocol for registration of all new agriculture crop varieties in order to confirm identity during the registration process and for subsequent use as a reference, if required. The decree stipulates that:

- DNA fingerprints of the new hybrid variety and its parents are a prerequisite for registration. One copy of the fingerprint is to be kept in the secretariat of the Seed Registration Committee and another copy is to be kept in the management office of the applicant's institution.
- The relevant crop technical committee should verify the fingerprint and its specifics through a laboratory certified to have the required scientific and technical capabilities.
- The applicant is to pay all costs required for the finger printing process, as determined by the registration committee for agricultural varieties. Sample material is to be submitted to the SRC secretariat, which will pass it to the relevant certified lab.

IPR in Egyptian Agricultural Research Institutes

Egypt's Law 132 of 1949 on Patents, Designs, and Industrial Models includes an explanatory memorandum that states that the word "industrial" includes the use of patents in agriculture. However, the memorandum excludes inventions of foodstuffs and pharmaceutical compounds, which encompass many genetic engineering applications, since the law allows only 10 years' protection for these. A recently proposed change to the IPR law expressly states that it applies to agriculture, foodstuffs, plant species, and microbiological processes and their products. Thus agricultural products and processes would be subject to protection as they are patentable subject matter.

According to patent records held at the Academy of Scientific Research and Technology, only one patent has been granted to Egyptian scientists in the field of agriculture. It was issued to scientists from AGERI for a biological insecticide gene isolated from a strain of the soil bacterium *Bacillus thuringiensis* indigenous to Egypt. The patent is the first to be obtained in Egypt for a biotechnology or molecular biology related product.

AGERI has recently drafted a proposed policy for handling IPR within the institute. The draft includes a statement of general policy clarifying assignment of IPR to AGERI; circumstances in which AGERI would release IPR to the inventor; and principles for handling royalties resulting from the licensing of protected IP.

In the proposed policy, the institute will hold all rights and title including, but not limited to, any disclosed invention, discovery, trade secret, technology, scientific or technical

development, license, computer software, institutional works, plant variety, data, research records, laboratory notebooks, etc., regardless of whether subject to protection under patent, trademark, copyright, or other laws. The policy is applicable to all units of AGERI and to all staff. The proposed policy may serve as a model for other institutes in ARC and other relevant organizations.

Regulations Affecting Technology Transfer, Transboundary Movement and Trade

In general, Egypt has not yet explored the trade implications of some GMO safety requirements. Further analysis is still required which could help enhance awareness, improve experience, and assist countries in strengthening their capacities for acquisition and transfer of GMOs and their products (Ingrassia 1997).

The Egyptian Constitution (Article 151) states that any international convention in which Egypt participates and ratifies becomes Egyptian law (El-Azab 1998). The most important international agreement that might affect the transfer and trade in GMOs is the so-called "international biosafety protocol." In January 2000, representatives of more than 130 governments finalized an international agreement that will regulate the safe transfer, handling and use of "living modified organisms" (LMOs) resulting from modern biotechnology. This "Cartagena Protocol on Biosafety" results from a decision by the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) in 1995, addressing the potential of biotechnology for human well-being, while at the same time taking into account the growing public concern over its potential adverse effects. The Protocol would enter into force after 50 countries have ratified the agreed text. To date, 68 countries have ratified the protocol. The Government of Egypt has not yet ratified.

The two cornerstones of the protocol are the concepts of "Advance Informed Agreement" (AIA) and the "Precautionary Principle". Through the Protocol, AIA enables an importing country to subject all first imports of LMOs to risk assessment before taking a final decision on import. The Protocol provides details on the whole process of notification, acknowledgment, and decision, which is supposed to be completed in 270 days. Detailed information will have to be provided by the importer on notification and LMOs should be clearly identified by accompanying documentation. In addition, the precautionary principle, as applied in article 11 of the protocol, asserts that

> "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."

In plain terms, including this principle allows countries to block imports of GMOs on a precautionary basis in the absence of sufficient scientific evidence about their safety.

Biosafety regulations for the release of GMOs have not yet been challenged under the GATT/WTO system. The acceptability, in principle, of scientifically based biosafety regulations should be guaranteed under Article XX ("General Exceptions) of the GATT

Agreement[3]. The same acceptability should also be guaranteed under the WTO's "Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures" (Ingrassia 1997). The SPS Agreement states that these protection measures have to be based on scientific principles and not maintained without sufficient scientific evidence. Nevertheless, the agreement allows countries to determine their own level of acceptable risk, responding to national points of view regarding what are necessary precautions.

Public Awareness and Acceptance

Global Context

The public will reap the benefits of biotechnology only by deciding that GMOs and transgenic food products will contribute to their well being. When the first GMOs were still under development, there was little discussion about public acceptance; it was, for the most part, assumed or in some cases dismissed as irrelevant. Exactly the opposite is true. What should have been a reasoned and informed debate over the appropriate use of biotechnology emerged instead as a prolonged exchange of often unfounded claims, charges, and countercharges between polarized factions.

The atmosphere of controversy surrounding GMOs and genetically engineered foods became even more turbulent during 1999. The scientific community started becoming more vocal and in some cases mounted point-by-point, science-based refutations of the more irresponsible opposition arguments. At the same time, industry proponents gained a small measure of credibility by acknowledging that the technology did have some limitations and inherent risks. Anti-technology groups, however, appeared increasingly well organized and well funded. They enjoyed progressively more coverage in mainstream media, capitalizing on the misuse of experimental data to support their claims. The barrage of publicity has undoubtedly raised public awareness but not acceptance. The subject of GMO safety has become the card that is played in order to get more fundamental issues on the table: control of our food supply, global equity in access to technology, farmers rights, world trade, and the like. In many countries, the public is demanding a more active role in determining what goes into the food supply, how it is produced, and by whom. Decisions to use biotechnology and its products are no longer considered the sole domain of those who make or regulate GMOs.

In Egypt

In the very earliest stages of Egypt's GMO research program, leading proponents recognized that public acceptance was essential for successful integration of biotechnology into the Egyptian agricultural system. Accordingly, they made a strategic decision that the first commercialized GMOs would be products of Egyptian national research institutes, rather than imported products grown commercially in their country of origin. In this way, the public's introduction to biotechnology would be in the form of preferred local varieties engineered to overcome local disease or pest problems – products developed 'at home' to benefit Egyptian farmers, growers, and consumers.

Research at AGERI flourished with strong support from the Minister of Agriculture. As recently as the summer of 1998, there was enthusiasm and confidence among the scientists, regulators, and industry people as the first transgenic crops neared commercial release. Consumer awareness was low, but those involved expected little objection due in large part to

[3] Full text available at http://www.ciesin.org/TG/PI/TRADE/gatt.html

the ‘all Egyptian’ strategy. By October of that year, however, there had been an abrupt turnaround in public opinion. Highly negative articles began to appear in newspapers, magazines, and on TV. Their inflammatory messages duplicated the more radical arguments seen and heard in Europe, India, and elsewhere. Lack of understanding in the media confused the public; many people came to believe that biotechnology products are tainted with plots and corruption.

The timing and strength of this anti-biotech media campaign apparently caught the biotechnology community completely unprepared. Months passed before biotechnology proponents began to mount a public response. So far, the response has been limited to newspaper and television interviews with, for example with the Director of AGERI, and publication of a series of general articles written by a member of the NBC. There is general agreement that not enough information is being distributed to counteract the misinformation; researchers feel that the government should use the media to inform the public from a neutral position. At the time of writing, the situation is considerably calmer. Negative comments and articles no longer appear in local publications, however the public hears anti-biotechnology messages from national and international media. Biotechnology research projects are continuing to progress and their number is expanding.

IV. THREE PRODUCTS APPROACHING COMMERCIALIZATION

Genetic engineering programs in Egypt started in 1990. Among the advances resulting from the biotechnology initiative are two crops now approaching the stage of commercial release. A third type of GMO, developed by two multinational companies, is also moving towards commercial release. The crops involved are:

- potatoes engineered to resist infestation by potato tuber moth, developed through a collaboration involving AGERI, the ABSP project, and the International Potato Center’s (CIP) regional office in Egypt;
- squash plants resistant to a major viral pathogen, resulting from cooperation between two Egyptian research institutes, AGERI and the Horticulture Research Institute, and the ABSP project;
- yellow and white varieties of maize modified for resistance to stem borers, independently produced by two international companies – the first GMOs being imported into Egypt for the purpose of field trials.

These three products were the basis for examining the organization and operation of Egypt’s biosafety system.

Insect Resistant Potatoes

Egypt produces about 2 million metric tons of potatoes, 60% of which are grown by small-scale farmers. Seed potatoes are imported primarily from Europe and the US. Only 250,000 metric tons are exported, mainly to the UK, France, Germany and Arab countries. One constraint to potato production is the potato tuber moth (PTM). This insect pest mines the leaves of plants, stunting them and leading to a reduction in stand. Field losses may be up to 30%. To make the situation worse, PTM is also a problem in stored potatoes, where larval tunneling render the tubers unfit for sale. To counteract storage losses, potatoes are dusted

with large amounts of toxic organophosphates like parathion. Thus potatoes sold from storage carry substantial pesticide residues. Development of potatoes resistant to PTM is expected to reduce the need for the pesticide applications in the field and in storage and to increase potential export volume by as much as 15%.

In 1992, collaborative research projects were initiated at AGERI under the auspices of the ABSP project to address specific commodity constraints. One of the objectives of the project was to develop transgenic potato plants expressing genes for insecticidal proteins derived from *Bacillus thuringiensis* (Bt). The genetically modified lines were to be used as parental material in breeding improved potatoes resistant to PTM. Selected lines would subsequently be used in a breeding program directed toward varietal development.

A team from AGERI and MSU identified a Bt gene active against PTM and suitable for use in transformation of potatoes. Important Egyptian varieties have now been transformed and tested. AGERI's project leaders requested and received approval of the NBC for conducting small scale field trials of transgenic potatoes transformed with Bt genes Cry 1A(c) and Cry V. Permits were given each year between 1996 and 1999. Agronomic trials for seed registration were conducted at the CIP station in Kafir El Zayat.

The PTM resistant potatoes are now ready for commercialization and mechanisms to move them into the commercial arena are being explored. AGERI has contacted several private firms, particularly those having experience in micropropagation of potato.

Virus Resistant Squash

Squash (*Cucurbita pepo* L.) is reported to be cultivated on about 40,000 hectares and to produce about 568,000 tons of fruit for Egyptian and export markets in Europe. The major cultivar, Eskandarani, is highly susceptible to zucchini yellow mosaic virus (ZYMV), the most serious viral pathogen affecting squash, muskmelon (*Cucumis melo* L.) and other cucurbits. This virus drastically reduces the yield and quality of the preferred Egyptian watermelon variety Giza 1. Conventional control of ZYMV is based on insecticides to control its aphid vector, combined with field inspection and roguing; these strategies remain ineffective.

Plants of squash cultivar Eskandarani were engineered with the coat protein gene of ZYMV, together with a marker gene conferring resistance to the antibiotic kanamycin. The coat protein strategy has been successful for engineering virus resistance in many other crop-virus disease interactions. After transformation and regeneration, squash lines found to be resistant to kanamycin were grown under biocontainment conditions at AGERI. Successive rounds of evaluations for virus resistance were carried out under biocontainment, confined greenhouse conditions, and finally field conditions.

During the period 1996–99, seven permit applications for greenhouse and field trials of virus resistant squash were approved by the NBC. By the summer of 1999, virus resistance as well as horticultural characteristics in fourth generation plants were being re-evaluated in the field at Sids Station, Bani Sweif Governorate, and fifth generation lines were being evaluated under greenhouse conditions. While tests were expected to continue until the end of the year, large-scale production of highly virus tolerant squash seed was underway at the El-Dokki station. Once all the tests are completed satisfactorily, the project leader will request approval from the Seed Registration Committee to begin seed registration trials.

Insect Resistant Maize

(a) Application Submitted by Fine Seeds International

In July 1998, Fine Seeds International, a private shareholders entity affiliated with Novartis Seeds, requested approval for registration of a Novartis yellow hybrid maize genetically engineered for stem borer resistance through use of a Bt gene. This application was the first sent to Egypt's NBC by a private-sector company. The variety named was approved in the EU on December 18, 1996, under the number C/F/94.11.03.

Fine Seeds International submitted detailed documentation describing the genetic modifications in the maize inbred lines, including methods for gene insertion, characteristics of the vector, the origin and function of each constituent part of the inserted DNA, information on the maize line's genetic stability, food and feed safety assessment data, and environmental safety assessment data approved by international certified bodies such as the EU Scientific Committee for Food and the EU Scientific Committee for Animal Nutrition.

The NBC approved a permit application for field testing a variety of yellow maize in August 1998, and the Supreme Committee on Food Safety granted an import permit the following month. Subsequently, the NBC issued a Material Transfer Agreement submitted by Novartis and Fine Seeds International. No objections were raised for importing an experimental seed sample to be tested under Egyptian conditions, pending approval by the Food Safety and Seed Registration Committees.

When all approvals were obtained, 15 kg of genetically engineered seeds were imported in November 1998. They have been subjected to field trials under the supervision of a group of plant breeders, crop protection specialists, and molecular biologists. A certified laboratory in Egypt will confirm the prior food and feed safety assessment before final registration of the variety.

(b) Application Submitted by Pioneer Overseas Corporation

In November 1998, Pioneer Overseas Corporation applied to the NBC for permission to import seed of five varieties of white maize: two white hybrids not genetically modified and previously approved by the Seed Registration Committee, and three hybrids genetically modified with a Bt gene for stem borer control. The application package included reports from US and European agencies documenting the safety of these GM varieties for humans, animals and the environment. These agencies are:

1. Advisory Committee on Novel Foods and Processes (UK)
2. Environmental Safety Assessment Reports and Nutritional Assessment Criteria
3. USDA Animal and Plant Health Service (APHIS)
4. Commission of the European Communities

The application was reviewed by the Agriculture subcommittee of the NBC. The issue of long-term effects of exposure to Bt toxins on insect populations, widely considered a pressure that will accelerate the emergence of resistant individuals, did not come up during the deliberations.

During the course of this application, the Protocol for permit, registration, and release of genetically engineered plants was approved and signed by the Deputy Prime Minister and

Minister of Agriculture on November 25, 1998 (Decree 1648/1998). The Protocol defines the steps required and the responsibilities of the NBC, the Supreme Committee for Food Safety, and the Seed Registration Committee. A permit was approved for Pioneer to import 15 kg of GM seed. The seeds were received in mid-1999 and inspectors were assigned to supervise seed registration testing as specified in the Protocol.

V. EVALUATION AND FINDINGS

Based on the information collected through the series of interviews and the review of relevant documents and applications, this section presents the main findings regarding the implementation and functioning of the various elements of Egypt's biosafety system.

Biosafety Guidelines

Egypt's biosafety guidelines for greenhouse containment and field tests were drafted by AGERI scientists, based on existing guidelines from the US and Europe, and were issued by Ministerial Decree in 1995. They direct the NBC to provide technical advice to regulatory authorities and researchers. The guidelines have been supplemented by subsequent decrees and protocol documents that provide clearer, stepwise descriptions of administrative procedures for field testing, seed registration, and commercial release.

The guidelines are general in nature, providing suggestions and recommendations for establishment of a biosafety system. Details are needed as to the principles, goals, and objectives of the system in Egypt, the basis for review and decision making, post-trial follow-up activities, reporting, and record keeping; these could be added as supplements. For commercial releases, some of the relevant information is derived through other agencies, in particular the Seed Registration Committee. As a result, the guidelines may lead to confusion on the part of applicants and IBCs.

The guidelines call for the establishment of an NBC, which is charged with publishing NBC Guidelines. Presumably these would be more comprehensive and complete than the current decree. The subject was not raised, however, by any person during any interview or conversation.

The text of the Section II, Part 3 entitled "Biosafety Guidelines" provides brief, uneven lists of recommended practices for research in laboratories, the containment greenhouse, and small-scale field trials. This part could mislead applicants who may believe compliance with the listed recommendations is all that is required.

The existence and function of the NBC and availability of biosafety guidelines have not yet been widely publicized. In addition, the Ministerial Decree for commercial release, which became effective November 25, 1998, is not yet widely known or available to relevant organizations, institutes, and individuals, particularly in the private sector. Measures to publicize the guidelines and commercialization protocol are being considered.

National and Institutional Biosafety Committees

The initial NBC, a group of 10 representatives of government ministries, has grown to a current membership of 30 divided among three specialized subcommittees. Expansion of the committee has brought in significantly more technical expertise. At the same time, the NBC has yet to include any "non-technical members who represent the interest of the surrounding community" as specified in the guidelines.

It has become apparent that some institutions conducting GMO research have not yet notified the NBC of their activities. In other cases, institutions with ongoing GMO projects have not yet established an IBC. Information gathered during the study indicates that probably none of the institutes or universities have written institutional guidelines. It is possible that these lapses are due to a lack of awareness.

The Ministry of Agriculture now allocates funds to carry out NBC activities. However the support services needed to keep the NBC abreast of developments in risk assessment and biosafety continue to grow, taxing the limited funds available. For example, a mechanism for disseminating new information to NBC members, from the scientific literature, conference proceedings, or relevant international activities, is not yet in place and will require additional funds. Funding to support participation at biosafety meetings and conferences is not available.

Review Procedures and Decision Making

A single standardized application form is used to request approval for a variety of activities: limited movement, limited importation, greenhouse use, and small-scale field tests of either GMOs, exotic materials, transformed biological agents, and "others;" definitions are not given. The applicant is asked to supply (1) the name of donor and recipient organisms (examples given are "BT, CP" for donor, "potato clone" for recipient); (2) the physical state of the inserted genetic material; (3) the name of the vector; (4) details of the transformation construct; and (5) other information, detailed on a separate paper.

During the course of reviewing selected applications for field tests, relevant biosafety issues were not raised. For example, potential outcrossing between transgenic squash and related species growing in the vicinity was not addressed. In small-scale field tests of crops with Bt genes for insect resistance, emergence of target pests resistant to the Bt insect control protein is not an issue due to the limited area and short time of such releases. Insect resistance is, however, a serious concern wherever Bt crops are grown on a large scale and over successive seasons. New data and ongoing research in this area have prompted US regulatory agencies to work together to revise standards for required resistance management plans for commercial Bt crops and regions[4]. Based on interviews with applicants and NBC members in Egypt, this issue has not come up in any discussions to date concerning Bt potatoes and maize approaching commercial release. According to the applicant from Fine Seeds International, "That is the weak link – there is little awareness. If it is ever raised, it would be by Novartis acting through Fine Seeds."

[4] US Environmental Protection Agency's letter to Bt corn registrants, dated 12/20/99. http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_corn_ltr.htm

Delays during the application and review process may raise barriers to product development. In addition, applicants unaware or uninformed of approval requirements for importing or growing GMOs may submit belated requests for biosafety approval, causing delays in their testing schedule. This was the case for Fine Seeds International, which missed a planting deadline due to late submission of their request to import Bt maize seed for testing.

Seed Registration Procedures

The standard testing procedure for registering conventional crop consists of trials over three years (or three growing seasons) to document the uniformity and agronomic performance of new varieties. The same requirement, which applies to both locally developed and imported crops, will be applied to GMO varieties as well. Thus the SRC uses uniform and consistent criteria for approving any new crop for commercial use. For GMOs, the testing serves also to evaluate certain characteristics and effects pertaining to environmental safety.

The Bt maize lines approaching this point in the commercialization process have raised a new issue regarding the SRC requirements. Both the Pioneer and Fine Seeds (Novartis) GMO varieties were developed in parental lines that were already registered in Egypt. In the companies' view, addition of a Bt gene changes the phenotype to insect resistant, but does not change the line's other characteristics. They contend that GMOs derived from registered lines should not be subject again to the full testing scheme. The SRC has taken the position that insertion of a new gene makes the lines "new" and therefore subject to the full three-year's testing. At present there is no procedure for streamlined or accelerated seed registration testing.

The extent of biosafety data that can be derived from performance testing should not be overstated. Unless a trial includes a properly designed and controlled biosafety study, only observations can be made. Presumably any potential short-term negative effects are evaluated during the small-scale field-testing phase; long-term effects will not show up in a three-year trial.

Building Public Awareness, Opinion, and Acceptance

In Egypt, as in most developing countries, there is no official information strategy for informing the public about GMOs and biosafety. The normal difficulties of mounting a public information campaign, such as determining who should do it, what approaches would be most effective, and who should pay for it, are compounded in Egypt where nearly 40% of the people are illiterate. Furthermore, there is no strong tradition of public empowerment in which consumers demand information and assert their "right to know" about genetically engineered foods.

The recent politically motivated opposition campaign in the Egyptian media unquestionably raised public awareness about biotechnology with the intended negative effect on public opinion. Lack of preparedness for the unexpected attack was evident in the slow and limited response from the biotechnology community. The result has been a greater awareness among researchers of the need for a program to disseminate fair and accurate information. Current low levels of NGO activity in Egypt cannot be assumed to continue in coming years. Public concerns as expressed in Europe and the USA are affecting agricultural markets around the world, and countries seeking to use the technology need to prepare public information

materials. It should be noted that the extent of public awareness and the scope of public information campaigns vary among differing cultures. As a further consideration, government information policy may affect the nature and success of information programs.

VI. RECOMMENDATIONS

Following the review of biosafety policies and procedures in Egypt, major recommendations of this report are summarized as follows:

1. Revise or re-issue the biosafety guidelines.
2. Establish and Fund a Secretariat for the NBC.
3. Institute mechanisms to disseminate information to the biotechnology community.
4. Develop a pro-active plan for building public acceptance.

1. Revise or Re-issue the Biosafety Guidelines

The NBC should take the lead in revising the current Biosafety Regulations and Guidelines, or in drafting NBC Guidelines, which would replace the existing document. New guidelines should describe the purpose and objectives of biosafety review and how it fits into the larger scheme of agricultural product development. Procedural and facility requirements for laboratory, greenhouse, or field research should be either comprehensively described or, more practically, provided through reference to other documents.

Step-by-step procedures for requesting NBC approval for field tests and commercial release should be spelled out so that applicants have a clear “road map” of the entire process. More detailed descriptions should be provided of the types of information to submit with applications; some countries, e.g., Australia, do this very effectively by providing a comprehensive list of questions for the applicant to answer. Instructions, sample application forms, and contact information should be provided.

Careful decisions should be made as to how the new guidelines could be vested with some degree of legal authority, how to ensure compliance, and if deemed appropriate, what sanctions could be imposed on institutions not in compliance. Consideration should be given to formally informing the NBC prior to starting any genetic engineering research. Initial contact prior to the start of activities would facilitate NBC record keeping. All institutes, organizations, and private companies that are or are likely to work with agricultural GMOs should be informed about the biosafety system, its operations and approval procedures. A simple packet of documents and ancillary information could be assembled for this purpose.

2. Establish and Fund a Secretariat for the NBC

A Secretariat should be instituted to manage administrative matters for the NBC. This office would serve as an information resource to NBC and IBC members, individual scientists, and potential domestic and foreign applicants. It would establish a means to disseminate information and promote cooperation with other national or international biosafety organizations and initiatives. It would accept and process applications, coordinate reviews, keep written records, and create a database of applications received and their status. The

Secretariat would set up and maintain a Website that carries all relevant documents, forms and instructions in a downloadable format. Preferably, both Arabic and English versions would be provided.

Several funding sources should be considered, keeping in mind issues of equity and public perception. Financial support could come through a percentage allocation of the total Academy of Scientific Research budget for biotechnology, a consortium of involved Ministries including the Ministry of Agriculture, the Egyptian Academy of Science and Technology, fees collected from applicant institutions and companies, or a combination of sources.

With the present subcommittee structure, the NBC actually functions as three independent review committees; recommendations, however, are put forward under the authorship of the whole. A more efficient organization would be achieved by using ad hoc technical reviewers to evaluate applications and make recommendations to a streamlined decision-making committee of no more than 10 or so members. This arrangement offers several benefits; it would (1) reduce the size of the committee to a core group actively involved in and responsible for ensuring biosafety; (2) provide a wider pool of technical experts and greater flexibility in selecting reviewers; (3) strengthen the scientific basis for decision making while diminishing other influences; and (4) stimulate compilation of a national inventory of technical experts which would be useful in other activities such as research coordination.

Lack of information about regulations and procedures can impede the course of GMO utilization. All parties – academic and government scientific organizations, the local private sector, multinational companies – should be made aware of the NBC and its role in GMO research and product development, as well as requirements for compliance with the guidelines. The protocol for commercialization of GMOs should be widely disseminated.

Under the current guidelines, IBCs have only a limited role as watchdogs and reporters within the system. Their role would be strengthened, and demands on the NBC would be lessened by delegating to IBCs full responsibility for approval of laboratory and greenhouse research at their institutions. IBC members should have training in risk assessment and risk management procedures. Open channels of communication with the NBC and the Secretariat should be instituted.

3. Institute Mechanisms to Disseminate Information to the Biotechnology Community

There is a critical need for risk assessment data in all countries seeking to use agricultural biotechnology. Sound biosafety decision making, particularly regarding commercial releases of GMOs, can be seriously hampered by a lack of scientific knowledge. Priority areas for risk assessment studies targeted to Egyptian conditions should be identified. For example, what is known about the effects of various Bt proteins on natural populations of insects in Egyptian maize fields? What is the best strategy for delaying the emergence of pest resistance to Bt? What is the distribution of related weed species known to cross with crops species being genetically engineered? Research institutes should actively promote projects in these areas. Risk assessment research funding could come through a set-aside of the Ministry of Agriculture's biotechnology research budget; alternatively, such studies could be funded by the applicant's institute or company.

Biosafety reviewers should receive support to attend international conferences on risk assessment, environmental and food safety, and public awareness. Subscriptions to selected print and on-line journals should be placed through the NBC Secretariat, which would bear responsibility for distributing copies of relevant articles to reviewers.

To facilitate planning and procedural transparency, realistic time limitations for application review and decision making should be specified.

National or private laboratories appropriate for certifying molecular and food and feed safety data should be identified and subject to certification. Qualified laboratory staff should have the capacity to work at the level of internationally accepted standards. In the interim, safety data generated by qualified labs outside of Egypt should be deemed acceptable by biosafety authorities. This is especially important during the period when local labs are building the necessary expertise for such studies.

As described in this report, the road to commercialization involves the National Biosafety Committee, the Supreme Committee for Food Safety, and the Seed Registration Committee. Presently, there are some overlaps among the members of these committees, which, though perhaps due to limited human resources in biotechnology, may undermine the validity of independent reviews. The remedy for having individuals serve multiple functions lies in long-term capacity building to alleviate the shortage of technically qualified people.

In some cases, committee members also appear in the role of applicant seeking committee approvals. This situation has the potential to erode public confidence in the biosafety system unless the applicant officially refuses himself from serving on any of the review committees and taking part in the discussions.

4. Develop a Proactive Plan for Building Public Acceptance

The public holds the fate of biotechnology in its willingness or refusal to accept products produced through genetic engineering. Thus it is essential to organize a campaign to inform the public about all aspects of biotechnology. The communications effort should be based on a recognition that the public is a full partner in deciding if, when, and how the technology is to be used. The first step is to develop a strategy for building public awareness and acceptance, preferably before misinformation from other sources takes root in public opinion.

Science editors and TV broadcasters need to be educated. Editors not only transfer the ideas of scientists, but also act as filters of that information. It is essential that these communicators understand basic science and are educated about biotechnology. Although some efforts have been undertaken in 1999 with support from UNEP, these should be repeated periodically. One way to support a public awareness campaign is through a fund under NBC administration. Effective spokespersons should be cultivated through training in the field of risk communication.

Labeling of GMO-derived foods is gradually gaining wider acceptance worldwide, and is viewed by many as inevitable. Authorities should begin now to plan how labeling will be handled in Egypt. The subtle warning found in the text promoted by opposition activists, “This product may contain ingredients derived from genetically modified organisms,” provides no useable information and would appear on the majority of processed foods. Instead, labeling should be viewed as an opportunity to present the benefits of biotechnology,

using phrases such as “Ingredients in this product were derived from biotechnology crops that are grown with more environmentally protective methods and fewer harmful chemicals.”

CONCLUDING REMARKS

The recent conclusion of negotiations leading to the adoption of the international “Cartagena Protocol on Biosafety”[5], poses a challenge to developing countries who have yet to implement biosafety policies and procedures. Starting in 1993, Egypt has made remarkable progress in designing and implementing a national biosafety system in a relatively short period. Using existing guidelines and involving international experts, AGERI spearheaded the development of a flexible biosafety system. In the period 1995–99, 24 applications for contained or open field trials were reviewed by the NBC and 23 permits were issued. Three genetically-modified crops are moving toward commercial release. As the review system matures, insight is gained on its strengths and weaknesses. Our analysis of Egypt’s biosafety policies and procedures resulted in recommendations for improving the efficacy of the biosafety system, which will also be most valuable to countries that recently established, or are about to establish, their own review systems.

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[5] http://www.biodiv.org/biosafe/index.html

ANNEX 1. INTERVIEW QUESTIONS FOR ISNAR BIOSAFETY STUDY IN EGYPT

Questions for Applicants Submitting Proposals

A. Awareness

1. What information about biosafety for transgenic products have you received from your institution?
2. What biosafety conferences, workshops, or other such meetings have you attended?
3. What do you see as the potential risks associated with the crop you want to commercialize?
4. Does the management at your institution have the same or different views on the potential risks?
5. What, in your opinion, is the attitude of farmers, growers, and distributors towards this or any other transgenic crop?
6. How would you describe public awareness and attitudes towards growing transgenic crops? towards buying and eating genetically engineered food?
7. How will you or your institution inform farmers, growers, distributors, and the public about this product?

B. Field Testing

8. When and where have small-scale field tests of this crop been conducted?
9. What information and data did you submit in applying for approval to conduct field tests? (copy of application)
10. What requirements or restrictions were imposed by the IBC or NBC? (copies of documents)
11. From the time of submission, how long did it take to get approval or denial of your request?
12. What monitoring was done?
13. What sort of reporting was required?

C. Commercial Release

14. What information did you submit in applying for approval for commercial release? (copy of application)
15. What additional information, if any, did the IBC or NBC request?
16. From the time of submission, how long did it take to get approval or denial of your request?
17. What requirements or restrictions were imposed by the IBC or NBC? (copy of documents)
18. Describe your interactions with the NBC.

D. Looking Forward

19. What specific changes in the biosafety system would allow you to work more effectively and efficiently? (make your job easier)
20. What is the marketing strategy for this product?

Questions for Biosafety Committee Members

A. Awareness

1. What information about biosafety for transgenic products have you received from your institution or the secretariat of the committee?
2. What biosafety conferences, workshops, training courses, or other such meetings have you attended? (sponsor, topics, length, audience, etc.)
3. What, in your opinion, is the attitude of farmers, growers, and distributors towards this or any other transgenic crop?
4. How would you describe public awareness and attitudes towards growing transgenic crops? towards buying and eating genetically engineered food?
5. What other companies or institutions have signaled their intent to commercialize their products?

B. Biosafety Review

6. With respect to the products nearing commercial release, what specific biosafety issues were raised by each case?
7. After review, what was the Committee's position on those issues for each case?
8. What conditions or requirements, if any, were imposed on the field test or commercial release?
9. What records must be kept? by whom?
10. What level of reporting to the IBC or NBC is required?
11. How is the review process different for import applications vs. release applications?
12. How is the review process different for applications coming from the public sector vs. the private sector?
13. To what extent does a company's "track record" in other countries affect decisions for Egypt? (e.g., history of cooperative and responsible interactions with Egyptian authorities; compliance with terms of approval for field test and commercial releases; linkage to an Egyptian entity; decisions made by regulatory authorities in the US, Europe, Latin America, Asia)

C. Looking Forward

14. What specific changes in the biosafety system would allow you to work more effectively and efficiently?
15. What problems do you anticipate as the number and variety of applications increase?

ANNEX 2. INTERVIEWEES AND CONTACTS

Dr. Atef Shoukry, Horticulture Research Institute, ARC; lead scientist in field testing virus resistant squash; applicant for commercial release.

Dr. Adel Yaseen, Chairman, Fine Seeds International (private company linked with Novartis for importation of Bt maize); applicant for commercial release.

Dr. Hanayia El-Itriby, Deputy Director for Research, AGERI; member of NBC Agricultural Sub-Committee.

Dr. Nabil Khamis, Research Station Manager, Pioneer Overseas Corporation Commercial Branch; applicant for commercial release of Bt maize.

Mr. Hisham El-Shishdawey, Biosafety Officer at AGERI; chair of IBC; manager of containment greenhouse; oversees field tests and field worker training.

Dr. Taymour Nasr El-Dinh, project leader for developing and testing Bt potatoes at AGERI; also interviewed as member of IBC and field test inspector appointed through Seed Registration Committee.

Dr. Abdel-Wahab Hafez, Professor of microbiology and former Head of Ain Shams University; member of the NBC Agricultural Sub-Committee.

Dr. Abdallah Molokheya, Ministry of Health and member of the NBC Health Sub-Committee.

Dr. Hassan Moawad Abdel-Al, Director, Mubarak City for Scientific Research and Technology Applications; member of the NBC Environment Sub-Committee.

Dr. Ramzy A. El Bedewy, International Potato Center (CIP)/Egypt; outgoing head and country representative.

Dr. Hassan Kasem Mohamed Bekheit, Plant Protection Research Institute; incoming head and country representative to CIP/Egypt.

Dr. Magdy Madkour, Director, AGERI; member of Seed Registration Committee; member of Supreme Committee for Food Safety; member of NBC Agriculture Sub-Committee.

ANNEX 3. POLICY, PROCEDURES AND PROTOCOLS FOR RELEASE OF CROP VARIETIES DEVELOPED BY THE AGRICULTURAL RESEARCH CENTER (ARC)

PURPOSE

The development of improved crop varieties is among the most important and pivotal outcomes of public investment in agricultural research. Their rapid and orderly adoption by farmers in the areas of adaptation is in the high interest of the rural economy and the public welfare. Decisions on how and when new varieties are released for seed multiplication and distribution to farmers have great influence on the rate and extent they are adopted and put into production. The purpose of this statement is to establish policy and provide guidance on procedures and protocols for the release of crop varieties developed by ARC to ensure that they contribute significance to the reforms and goals of the agricultural sector and that the potential benefits from adoption of the varieties by farmers are fully realized.

1. DEFINITIONS

In these policy and procedures statements, the meaning of the terms “public variety release," “variety release procedure” and “qualified seed producer” are as defined below:

1.1 Public variety release is a term for:

- a mixed pollinated variety for which foundation seeds can be released annually;
- a self pollinated variety for which registered seeds can be released. A self pollinated foundation variety can be released upon recommendation of VRAC and approval of the Deputy Prime Minister and Minister of Agriculture.

1.2 Variety release procedure is a collective term that can have one or more of the following meanings, depending on the context of its use: the type of release; the terms and conditions attached to the release; the protocols followed and the administrative procedures used in releasing a new publicly developed variety by ARC.

1.3 A qualified seed producer is a seed producer or seed company that is licensed for seed production in conformity with the conditions and requirements in Ministerial Decree No. 38 of 1997, Article 4 and/ or any related amendments.

2. VARIETY RELEASE POLICY AND PRINCIPLES

2.1 Registered and Released Varieties. The type and conditions of release for varieties released prior to the effective date of these policies and principles shall remain in effect, with respect to any contract or obligations previously approved by MALR.

2.2 New Registered Varieties. New varieties of all crops developed by the ARC shall be released after completing the registration process in accord with the policy, principles and protocols decreed herein and the administrative procedures established by the competent authority designated in Section 2.3 as responsible for their formulation and implementation.

2.3 Authority and Responsibility for Release of Public Varieties. The authority and

responsibility for carrying out these policies and protocols relating to the release of ARC varieties (including the formulation of additional protocols as necessary and administrative guidelines for their full implementation) are vested in the Director of the Agricultural Research Center through a Variety Release Advisory Committee (VRAC) appointed by Minister of Agriculture.

2.3.1 Membership of the VRAC. The VRAC shall consist of nine (9) members: Chairman ex officio (Director of ARC); three (3) additional members from ARC; three (3) members from the private sector including one from ESAS; one (1) member from CASC; and one (1) member from the Association of Egyptian Plant Breeders. The terms for all members except the Chairman ex officio shall be two (2) years. The Chairman ex officio shall appoint a recording secretary to maintain records of the VRAC and perform administrative work.

2.3.2 Principal duties of the VRAC. The principal duties of the VRAC shall be:

a) Recommending specific variety release procedures for newly registered varieties (Sections 2.5 and 2.9).
b) Tendering or auctioning varieties recommended for exclusive release (Section 2.8).
c) Evaluating proposals to the public tenders of varieties with selection of the best or "winning" proposal (Section 2.9.2) to be concurred by Minister of Agriculture.
d) Beginning discussions and hearings leading to a recommendation of the release procedure for a candidate variety till its approval (Section 2.4.2).
e) Following up ongoing variety release contracts. If needed, VRAC can invite some specialists to participate in some meetings, without voting, and also to prepare alternatives for variety release before its registration.

2.4 Variety Release Options. The VRAC shall recommend one of the two variety release options specified in this section for each variety submitted to it for action. In exceptional circumstances and with adequate justification, it may recommend a variety release procedure different from the two options specified.

2.4.1 Open or General Release of the Variety. Open release of the variety means approval of its commercial production of its seeds by applying all certified procedures, according to the approved conditions and procedures given in Section 2.9.1.

2.4.2 Exclusive Release of the Variety. An exclusive release shall be awarded to a qualified seed producer (Section 1.3), based on an evaluation of proposals or bids received in response to a public tender or auction of the variety. The period, terms and conditions of the release shall be set forth in a Material Transfer Agreement between the ARC or the relevant research institute and the entity granted exclusive success to foundation or equivalent seeds of the variety. The quantity of foundation seeds produced and available for release and the terms of release (e.g. price, down payment, royalties and fees) shall be specified in the exclusive release agreement.

2.5 Selection of the Variety Release Procedure. The over-riding principle in decisions and actions regarding the release of a public variety shall be the public interest and welfare in terms of benefits to both the producers and consumers of the produce of the variety. Several factors and circumstances need to be considered in deciding on the release procedure for a

specific variety to assure adherence to this and other stated principles and to support and advance other reforms and objectives in the country's agriculture sector (e.g., a competitive, market-oriented input supply.)

In case of availability of frequent varieties, and for close similarities, so exclusive release might be recommended. As a general rule, all hybrid varieties should be released on an exclusive basis, while non-hybrid varieties of self-pollinated crops may be released either as an open or general release or as an exclusive variety release, depending on the specific factors and circumstances enumerated below. Availability of a small number of varieties and/or significant superiority of a certain variety in an important trait (e.g. productivity, adaptability, pest control) suggests that a general release can be recommended.

2.6 Control and Maintenance of Public Varieties. The ARC and its research institutes and programs shall retain control of the variety and be responsible for maintaining the variety, producing breeder and foundation seeds and distributing breeder and/ or foundation seeds according to the variety release procedure adopted by ARC.

2.7 Sale of Seeds and Royalties. Foundation and/or registered seeds shall be determined, putting in consideration its costs and the price of certified seeds. A reasonable schedule of royalties shall be levied on all new public varieties to supplement the support available for breeding, variety improvement and related research in the research institutes and programs of ARC and to provide substantial incentives for continued productivity of the scientists involved.

2.8 Public Announcement of Intention to Release a Variety. When the release procedure for a variety is approved, a public announcement of the release shall be made by the VRAC. The announcement shall contain a general description of the variety, its advantages over varieties in present use, its areas(s) of adaptability, whether general or exclusive release the technology package needed for the variety, and the variety release procedure adopted.

2.8.1 Open or General Release. When an open or general release procedure is adopted for a variety, the announcement should specify the time and procedure for requests for foundation seeds from qualified seed producers, the price of the foundation seeds, and the schedule of royalties or fees.

2.8.2 Exclusive Release. When an exclusive release procedure is adopted for a variety, the initial announcement shall direct interested and eligible parties (e.g. companies, cooperatives, associations) to the VRAC for a detailed technical description of the variety and full information on and access to the public tendering or auction of the variety(Sections 2.9.1 and 2.9.2).

2.9 Protocols and Procedures for Exclusive Variety Releases. The process of awarding an exclusive variety release shall be public, in accord with the policies, principles and protocols enunciated herein and administrative procedures established and published by ARC, the designated authority. This process should be fully transparent, equitably applied, and accessible to all interested and qualified parties. The conditions for general and exclusive release are given below.

2.9.1 Procedures for General Release. Foundation or registered seeds should be available for any registered seed procedures. In the first year, the contract should state

the availability of requested quantity of seeds, putting in consideration the producer's experience, history, performance during production of this variety seeds. Requested seeds will be available, provided that application is submitted early enough, stating quantity required every year, expected quantity to be produced from each generation and numbers of generation, production conditions, geographical distribution of the variety, price, royalties and other items.

In case of failing any of the contract conditions, especially increase in agreed number of generations mentioned in the contract, might subject contractor for penalties given under Section 2.10, as well as refusal of special management ------- in Ministry of Agriculture.

2.9.2 Conditions, Procedures and Evaluation of Bids for Exclusive Release.

a) Eligibility. An entity holding an exclusive rights award for a variety shall not be eligible to participate in the competition for tendered varieties of the same crop during the period of the initial award, viz., the first 5 years, provided, however, that eligibility shall be restored after the initial period regardless of whether the renewal option for a second period of exclusive rights is used.

b) Terms.

1) The period of the exclusive release shall be ten (10) years with original holder given first priority for renewal for a second period, provided its performance has been satisfactory and it is interested in retaining exclusive rights.

2) The schedule of royalties and the method of calculation shall be clearly stated.

3) Mentioning the minimum amount of commercial seeds to be produced.

c) Information/Data Required from the Applicant. The following are the principal criteria used for evaluation of applications. A suggested weight for each is given in multiples of **X**).

- The organization, seed production/ marketing experience, capabilities, production and processing locations and capacities owned or leased, and marketing areas of the applicant for the kinds of seeds it produces and markets. (**X**)
- Specific experiences and capabilities of the applicant in production, processing, and distribution/ marketing of seeds of the crop kind to which the tendered variety belongs. (**2X**)
- Promotional, activities, advertisements and dealer/customer service activities normally carried out by the applicant as part of its market promotion. (**X**)
- The production, distribution/marketing and promotional procedures the applicant proposes to use for the tendered variety if awarded the exclusive release. (**2X**)
- General pricing policy including the usual price for certified seeds of the crop to which the variety belongs as a multiple or percentage of the commodity price of the equivalent grain. (**1.5X**)
- Previous performance of the producer, as indicated in the official documents in the CASP. (**?X**)

d) Evaluation of Bids and Proposals. The committee members requesting release should be excluded from evaluation of bids to that variety. The information/data required from applicants in Section 2.9.1C shall constitute

the principal criteria for selecting the applicant recommended for awarding the exclusive release. For each of the five criteria, the evaluation shall be expressed on a ranked basis with 1 the lowest ranking and 9 being the highest ranking. A ranking of 0 shall be recorded for no response. Members of the VRAC shall produce independent rankings for each proposal received, which shall be averaged to determine the overall highest ranked proposal. In case of a tie in rankings, the proposal to be recommended shall preferably be decided between or among the applicant involved. Failing agreement of the applicants, the proposal to be recommended shall be decided on the basis of a drawing in their presence.

2.9.3 Review and Auditing of Holders of Exclusive Release. The performance of holders of exclusive variety releases shall be reviewed annually to determine if terms and specifications in the agreement are being observed and achieved. Deficiencies noted shall be directed to the attention of the holder of the release in question. Substantial deficiencies in performance or irregularities that are not corrected shall constitute sufficient cause for assessing penalties, which shall be rescinding the agreement, re-tendering the variety or declaring it an open release.

3. ADMINISTRATIVE PROCEDURES

3.1 ARC through the VRAC shall establish and publish additional protocols and administrative procedures as necessary, in conformity with the policies, principles and protocols set forth herein for their orderly and efficient implementation.

ANNEX 4. PROTOCOL FOR PERMIT, REGISTER AND RELEASE OF GENETICALLY MODIFIED PLANTS IN EGYPT

In November 1998, the Deputy Prime Minister of Agriculture and Land Reclamation, signed Act No. 1648/1998 for the protocol required for permit, register and release of GM plants in Egypt. This protocol illustrate the steps which should be followed, by government and /or private sector, as well as other local or foreign organizations dealing with the production of genetically modified plants with better traits. Before releasing any GM plant in Egypt, the steps should be as follows:

1. The applicant for commercial release of certain GM plant, should fill a "Permit Application Form". This form concerns with requesting release of genetically modified substances. Such form is available from the secretary office of NBC, located in AGERI/ ARC, Giza.
2. The applicant should fill the application form, in which he illustrate in details, all information on gene or genetic material that had been introduced to this variety, the process used for genetic modification, and the relevant information required in such form. The applicant should submit all relevant studies carried out to ensure biosafety status of this new variety, including environmental biosafety, food safety, ensuring absence of any risk hazard on human, animal, plant, environment. ALSO, he should submit documents to state that this GM variety had been approved for release in the country of origin.
3. The NBC secretariat - after receiving the Permit Application Form with all required information - will present the case to NBC in their following meeting for consideration and giving their opinion about preliminary approval or disapproval of releasing Ells specific GM variety and the scale for release (open field test, contained field test, green house trial...)

4. In case of NBC approval at certain scale, the following steps should be adhered to:

    - If this GM variety was locally produced in Egypt, the applicant will be allowed to start investigation within the approved scale only. NBC will assign who will officially inspect the experiments, either by the NBC members, or AGERI, or others. The inspectors have the right for periodical inspections to ensure safety measures in application and adheres to technical parameters required. NBC has the right to take samples of genetic material for molecular analysis to confirm the nature of the gene that had been introduced to this plant variety and also to check the extent of self gene expression in such variety.

    - If the GM variety was produced abroad and the foreign applicant or his representative in Egypt, request starting their investigations in Egypt at certain scale; as approved by NBC, then Develop a pro-active plan for building public acceptance the applicant should obtain a permit for importing limited amount of such variety (e.g. seeds), to be able to start his investigations, within the specific requested scale. In this case, the applicant should:
        - Submit request to the "Supreme Committee for Food Safety" at the Ministry of Public Health; provided that NBC has passed this Application. The application can be either in a form of a "Material Transfer Agreement" or any other form, provided that transparency and clearance are clear enough.

- After having the approval of the “Supreme Committee for Food Safety”, the applicant can start his investigations on the GM variety, within the approved scale only. NBC will ensure the inspection by NBC members and/or experts from AGERI or other relevant institutes; to ensure safety application and adoption of technical parameters and principals. The NBC has the right to take samples for molecular level analysis, and to ensure the nature of the introduced gene and the self gene expression in this specific variety.

5. After positive completion of field investigations on this GM variety under Egyptian conditions and ensuring all biosafety and environmental aspects, and if the application wish commercial release of such variety, the applicant can submit an application directly, to Seed Registration Committee, Ministry of Agriculture, requesting registration of this GM variety.

ANNEX 5. PERMITS ISSUED BY THE NBC: 1995–99

By Application Date

Date	Approval	Crop	Trait	Institute	Release Type
01/09/96	24/12/96	Musk melon, Squash	Resistance to ZYMV	AGERI / MSU	Biocontainment
09/09/96	24/12/96	Potato	Resistance to PTM	AGERI / MSU	Biocontainment
25/09/96	24/12/96	Potato	Resistance to PLRV	AGERI /SCRI	Biocontainment
09/10/96	24/12/96	Potato	Resistance to PTM	AGERI / MSU	Biocontainment
26/10/96	24/12/96	Tomato	Resistance to TYLCV	AGERI / ILTAB/ MSU	Open field
21/11/96	24/12/96	Potato	Resistance to PTM	AGERI / MSU	Open field
15/11/96	24/12/96	Sugar Cane	Resistance to SCMV	Sugar Crops Res. Inst.	Biocontainment
01/12/96	24/12/96	Musk melon, Squash	Resistance to ZYMV	AGERI / MSU	Open field
08/12/96	24/12/96	Potato	Resistance to PTM	AGERI / MSU	Biocontainment
10/12/96	24/12/96	Tomato	Resistance to TYLCV	AGERI -ILTAB/ MSU	Biocontainment
12/09/97	22/11/97	Potato	Resistance to PVY	AGERI / MSU	Open field
15/10/97	22/11/97	Potato	Resistance to PTM	AGERI / MSU	Open field
10/11/97	22/11/97	Musk melon, Squash	Resistance to ZYMV	AGERI	Open field
14/11197	22/11/97	Musk melon, Squash	Resistance to ZYMV	AGERI	Open field
17/11/97	22/11/97	Squash	Resistance to ZYMV	AGERI / MSU	Biocontainment
01/10/98	24/11/98	rDNA construct	Resistance to FMDV	Th. Bilharz Res. Inst.	Biocontainment
07/10/98	24/11/98	Potato	Resistance to PLRV	Max-Planck Inst.	Open field
10/10/98	24/11/98	Potato	Resistance to PTM	AGERI/MSU	Open field
04/05/98	07/07/98	Maize	Resistance to Cornborer	Novartis/Fine Seeds	Biocontainment
27/10/98	24/11/98	Maize	Resistance to Cornborer	Pioneer Hi-bred	Biocontainment
28/01/99	06/05/99	Squash	Resistance to ZYMV	AGERI	Biocontainment/Open Field
28/01/99	06/05/99	Melon	Resistance to ZYMV	AGERI	Open Field
28/01/99	06/05/99	Cucumber	Resistance to ZYMV	AGERI	Open Field
27/04/99	Pending	Maize	Resistance to Cornborer	Verneuil Semences	Open field

By Crop and Trait

Crop	Trait	No.	Appl'n. date	Approval	Institute
Potato	Resistance to PTM	6	09/09/96	24/12/96	
			09/10/96	24/12/96	
			21/11/96	24/12/96	AGERI/MSU
			08/12/96	24/12/96	
			15/10/97	22/11/97	
			10/10/98	24/11/98	
Potato	Resistance to PLRV	2	25/09/96	24/12/96	AGERI/Scottish Crop Research Inst.
			07/10/98	24/11/98	Max-Planck Institute
Potato	Resistance to PVY	1	12/09197	22/11/97	AGERI / MSU
Tomato	Resistance to TYLCV	2	26/10/96	24/12/96	AGERI/ ILTAB/MSU
			10/12/96	24/12/96	AGERI/ ILTAB/MSU
Squash	Resistance to ZYMV	8	01/09/96	24/12/96	
and/or			01/12/96	24/12/96	
Melon			10/l1/97	22/11/97	
			14/11/97	22/11/97	AGERI/MSU
			17/11/97	22/14/97	
			28/10/99	06/05/99	
			28/01/99	06/05/99	
Maize	Resistance to Cornborer	3	04/05/98	07/07/98	Novartis / Fine Seeds International
			28/10198	24/11/98	Pioneer Hi-bred
			28/01/99	Pending	Verneuil Semences
rDNA construct	FMD virus	1	07/10/98	24/11/98	Theodore Bilharz Research Institute
Cucumber	Resistance to ZYMV	1	28/01/99	06/05/99	AGERI
Sugar Cane	Resistance to SCMV	1	15/11/96	24/12/96	Sugar Crops Res. Inst.

ANNEX 6. PERMIT APPLICATION FORMS

NATIONAL BIOSAFETY ANNEX-FORM
(Submit this Annex with form)

Application No:-…….. Form No:- ……

PERMIT APPLICATION FOR GENETICALLY MODIFIED ORGANISMS (GMOs)

Applicant names:-
……..……..…….

Address:-
……..……

Telephone #:-……...

"X" one of the following in these coming questions:-

Permit request for:-	Permit for:-
Limited movement Limited importation Release to greenhouse Release for small-scale trial	Genetically Modified Organism Exotic materials Transformed biological agent Others (specify on a separate paper)

Means of movement:-	This is a:-
Mail Common carrier Baggage or handcarried	New permit Renewal permit Supplemental

Date required for importation, movement or release:-……..……...

Country of origin of regulated article:-……...

Arrival destination of movement:- …….……

Number, quantity or volume or regulated article:-…….……

Any biological material accompanying the regulated article:-……..…..

…….……

Signature of applicant Date

NATIONAL BIOSAFETY ANNEX-FORM
(Submit this Annex with form)

Donor organism (e.g. BT, CP):-

……
……..……..……..……

Recipient organism (e.g. potato clone):-

……
……..……..……..……

Physical state of inserted genetic material (integrated or extrachromosomal):-

……
……..……..……..……

Vector or vector agent:-

……
……..……..……..……

Give details of construct used to transform plant:-

……
……..……..……..……

……..……..……..……

Other information (give as much details in a separate paper):-

……
……..……..……..……

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PERMIT APPROVAL
NATIONAL BIOSAFETY COMMITTEE-EGYPT

Application No.:-…… Approved Rejected

If rejected, reason why:-

……
……

Prof. Dr. Youssuf Wally
Deputy Prime Minister,
Minister of Agriculture &
Land Reclamation, and
Chairman, NBC-EGYPT

Date

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